

# FOOD SAFETY PREVENTIVE CONTROLS FOR HUMAN FOOD

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One of the seven major rules of the Food Safety Modernization Act, the Preventive Controls for Human Food Rule, establishes Current Good Manufacturing Practices (CGMP), hazard analysis, and risk-based preventive controls for the production of human foods. The rule's purpose is to ensure that products are safe for consumption.

## REGULATORY BODIES

There are two federal bodies that majorly influence food safety plans and requirements: the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). The USDA is primarily concerned with meat, poultry, and eggs. The FDA is responsible for everything else. USDA requires a food safety plan that follows the HACCP concept (*See Fact Sheet 5.3 Hazard Analysis Critical Control Point for more information*). FDA requires a food safety plan that follows the Preventive Controls for either Human Foods or Animal Foods.

In addition to the regulations set out by federal bodies, you will need to follow Idaho state food safety requirements. The Idaho State Department of Agriculture (ISDA) and Idaho Health Districts may require either food safety system. Always check with these agencies about what food safety regulations affect you and your business.

## GOOD MANUFACTURING PRACTICES

The Preventive Controls for Human Foods Rule updated the Current Good Manufacturing Practices (cGMP). Good Manufacturing Practices (GMP) are the minimum sanitary requirements to produce a safe food product. GMPs include the following headings: personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, ware-

housing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels.

## FOOD SAFETY PLAN

The Rule requires that a facility (if you manufacture, process, pack, or hold human food for consumption in the United States) have a food safety plan that is compliant with the rule. Your food safety plan builds on the HACCP methodology with some additional requirements. (*See Fact Sheet 5.3 Hazard Analysis Critical Control Point for more information*). The following are some of the differences between HACCP and the Preventive Controls requirements.



## PREVENTIVE CONTROLS

In addition to prerequisite programs, the PC rule includes preventive controls to help significantly reduce or minimize hazards. Preventative control classifications include process controls, food allergen controls, sanitation controls, and other controls.

### PREVENTATIVE CONTROL CLASSIFICATIONS

**Process controls** include cooking/pasteurization, freezing/refrigeration, acidifying foods, etc.

**Food allergen controls** include how to ensure that the Big 9 allergens (milk, eggs, peanuts, tree nuts, crustacean shellfish, fish, soy, wheat, and sesame) are labeled if they are included in the food. If they are not, that no inadvertent cross contamination exposes your product to those allergens.

**Sanitation controls** are the procedures and program to ensure the facility and equipment is maintained according to sanitary design principles.

**Other controls** are those that significantly reduce or prevent the hazard from occurring but are not categorized in the previous preventive controls' classifications. metal, wood, stones, plastic, bones, rubber, and glass fragments are included.

## RECALL PLAN

A recall plan is required for all facilities that have identified any hazard that requires a preventive control. This includes most manufacturers, as most food production involves some level of hazard.

## QUALIFIED INDIVIDUAL

The person that oversees the food safety plan must have the training and knowledge to be considered a preventive controls qualified individual (PCQI). The requirements for becoming a PCQI are

outlined in the rule. The Food Safety Preventive Controls Alliance (FSPCA) (<https://www.ifsh.iit.edu/fspca>) has a standardized curriculum that is recognized by the FDA that can help you meet the requirements of a PCQI.

## HAZARD ANALYSIS CRITICAL CONTROL POINTS

Preventative Controls for Human Food relies on key principles outlined in Hazard Analysis Critical Control Point (HACCP).

### HACCP SEVEN KEY PRINCIPALS:

- ✓ Hazard Analysis
- ✓ Critical Control Point Identification
- ✓ Establishing Critical Limits
- ✓ Monitoring Procedures
- ✓ Corrective Actions
- ✓ Verification Procedures
- ✓ Record-Keeping & Documentation

## EXEMPTIONS

Not all facilities have to comply with all sections of the Preventive Controls for Human Foods (PC) rule. Retail stores, restaurants, and farms are not subject to the rule. Other facilities could be classified as qualified or exempt; those facilities must still comply with some sections like cGMPs and modified requirements. However, those facilities may not be responsible for all sections of the PC rule. Some reasons for exemptions include: low-risk on-farm activities, type of storage facilities, products already covered by other specific regulations (seafood, juice, low acid canned food, alcoholic beverages), or the size of your business. Visit the FDA website ([fda.gov](http://fda.gov)) or the Who Can Help section at the end of this chapter for more information.